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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,114	12/05/2003	Scott A. Burton	59098US002	3162

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EXAMINER	
GHALI, ISIS A D	
ART UNIT	**PAPER NUMBER**
1615	

NOTIFICATION DATE	DELIVERY MODE
07/20/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/729,114	BURTON ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *19,20,22 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :05/12/2005; 06/02/2005; 01/27/2006; 07/19/2006; 09/22/2006; 05/18/2007; 06/05/2007.

DETAILED ACTION

The receipt is acknowledged of applicants' election filed 06/05/2007, IDS filed 06/05/2007, IDS filed 05/18/2007, IDS filed 09/22/2006, IDS filed 07/18/2006, IDS filed 01/27/2006, IDS filed 06/02/2005, and IDS filed 05/12/2005.

Claims 1-23 are pending.

Response to Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-18 and 21, in the reply filed on 06/05/2007 is acknowledged. The traversal is on the ground(s) that the three groups can be evaluated in one search without placing undue burden on the examiner, and the groups are not distinct because claim 1 is generic to claims 19 and 20. This is not found persuasive because claim 1 is distinct from claims 19 and 20 because it does not require specific polymers and specific microparticles as required by claims 19 and 20. Invention I requires antimicrobial agent and additives that are not required by inventions II and III. Additionally, invention I requires specific particle sizes and specific aperture sizes of the substrate, and dispersion of the microparticles, all not required by inventions II and III. Therefore, the prior art that anticipates claim 1 may not anticipate claims 19 and 20. Additionally, the search system and the focus of the invention are completely different, requiring an undue burden on the patent examiner. While searches

may seem to be overlapping, however extensive since the patent examiner searches the databases mostly literally. Rarely do applicants present claims to an inventions where the distinctness of the invention are readily clear such as a chemical compound and a gene sequence. It is the responsibility of the examiner to enforce 35 USC 101, which allows the applicant to obtain a patent for a single invention. In the opinion of the examiner the applicants present three distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 19, 20, 22, 23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 06/05/2007.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-23 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-73 of copending Application No. 10/728,577. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: wound dressing comprising organic polymeric matrix and hydrophilic microparticles. The difference between the present claims and the conflicting claims is that the present claims recite substrate. The substrate is known in the art of wound dressing, and one having ordinary skill in the art would have provided substrate to support the polymer matrix. The present claims and the conflicting claims of the copending application are obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 4-6, 14 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" recited by claims 4-6 is a relative term which renders the claim indefinite. The term is not defined by the claim, and the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably recognize of the scope of the invention.

Claim 14 recites the limitation "polymer composition" in 1st line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 16, the expressions "compatibilizer", "extruding aid" and "chain transfer agent" do not set forth the metes and bounds of the claim. Recourse to the specification does not define the expressions.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-6, 13-18, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 02/066087 ('087).

WO '087 disclosed medical article comprising an adhesive composition comprising a polymeric matrix and absorbent particles of microcolloid particles (abstract; page 3, 7th paragraph; page 7, 1st paragraph; page 11, 3rd paragraph; page 12), and preferably the particle size less than 1 micron (page 4). The microcolloid particles form from 5-100% by weight of the adhesive composition (page 5, 3rd paragraph). The adhesive composition further comprises a plasticizer (page 14, 3rd paragraph; page 18, 2nd paragraph). The particles are dry powder, i.e. nonhydrated (page 5, last paragraph). The microcolloid particles of the composition delivered in a carrier liquid in the form of a suspension, as required by claim 13 (page 6, 1st paragraph; page 12, 9th paragraph). The particles are made of acrylic acid polymer (page 15, 1st paragraph; page 16, 4th paragraph). The polymeric matrix is preferably hydrophobic (page 6, 6th paragraph). The polymer matrix comprises S-I-S and S-B-S copolymers (page 17, 5th paragraph). The polymer matrix may contain combination of polymers (page 17, 3rd paragraph; page 18, 3rd paragraph). The adhesive composition is coated on porous substrate to form wound dressing that absorbs wound exudates (page 9, 2nd and 3rd paragraphs). The adhesive matrix further comprises active agents including antibacterial agents (page 19, 3rd paragraph).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '087.

The teachings of WO '087 reference are previously discussed in this office action as set forth.

While WO '087 teaches fine pore sizes of the porous substrate, it does not explicitly teach pore size of 1 mm to 0.5 cm as claimed by claim 8 or the number of the pores per square cm as claimed by claim 7. It is the examiner's position that the pore size and their number are result effective variables because changing them will clearly

affect the type of product obtained. See MPEP § 2144.05 (B). Case law holds that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Evidence to support the examiner's position is found in WO '087 in page 10, 1st paragraph, where the reference teaches that porosity can be controlled and higher porosity is advantageous.

Therefore, it would have been obvious to one of ordinary skill in the art to utilize appropriate pore sizes and numbers of pores of the substrate/square unite, including those within the scope of the present claims, so as to produce desired end results of moisture absorption and thereby arrive at the presently cited claims.

12. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '087 in view of the article "SALCARE® SC95" by Ciba®.

The teachings of WO '087 are previously discussed as set forth in this office action.

Although WO '087 teaches varieties of materials of the microcolloidal particles including acrylic polymers, however, the reference does not specifically teach the specific material of the microparticles as claimed by claims 9-11.

The article teaches that "SALCARE® SC95" is a cationic homopolymer dispersed in medicinal grade white oil. SALCARE® SC95 does not require pre-mixing or special equipment, has high thickening efficiency, and gives good uniform performance when incorporated in cosmetics.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide medical article comprising an adhesive composition comprising a hydrophobic polymeric matrix and absorbent particles of acrylic acid polymers as disclosed by WO '087, and replace the acrylic acid particles by SALCARE® SC95 particles disclosed by the article of Ciba®, motivated by the teaching of the article of Ciba® that such material does not require pre-mixing or special equipment, has high thickening efficiency, and gives good uniform performance when incorporated in cosmetics, with reasonable expectation of having medical article comprising an adhesive composition comprising a hydrophobic polymeric matrix and absorbent particles made of SALCARE® SC95, that is safe to the skin and easy to produce.

13. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO '087 in view of US 4,902,565 ('565).

The teachings of WO '087 are previously discussed as set forth in this office action.

Although WO '087 teaches varieties of materials of the microcolloidal particles including acrylic polymers, however, the reference does not specifically teach the specific material of the microparticles as claimed by claim 12.

US '565 teaches wound dressings having porous substrate that is preferably a foamed plastics material having interconnecting cells and advantageously having a fine pore size to provide greatest surface area and fastest water uptake (col.3, lines 6-15). The substrate comprises solid water absorbing particles that are preferably finely

powdered, having high water absorbing and retaining properties. Examples of suitable polymer materials are polymers or copolymers of acrylamide or polymers of one or more acrylic monomers with acrylic or methacrylic acid. When unsaturated acid monomers are employed, the acid groups may be neutralized by treatment with an alkali metal hydroxide, such as sodium hydroxide, which reads on the copolymer of claim 12. Preferably, the particulate, water-absorbing material has a particle size of less than 50 microns (col.2, lines 1-21).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide medical article comprising an adhesive composition comprising a hydrophobic polymeric matrix and absorbent particles of acrylic acid polymers as disclosed by WO '087, and replace the acrylic acid particles by particles comprising copolymer of acrylate salt and acrylic acid as disclosed by US '565, motivated by the teaching of US '565 that such particles have high water absorbing and retaining properties, with reasonable expectation of having medical article comprising an adhesive composition comprising a hydrophobic polymeric matrix and absorbent particles of copolymer of acrylate salt and acrylic acid that has high water absorption capacity and retaining properties that are advantageous to the wound dressing and wound healing.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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PRIMARY EXAMINER